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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/432,820 11/02/99 KAPOOR A A-57004-4/RF

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NM12/1023

EXAMINER

ZARA, J

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/432,820

Applicant(s)

KAPOOR ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-50 is/are pending in the application.
- 4a) Of the above claim(s) 34-40 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50 is/are allowed.
- 6) ☒ Claim(s) 24-33 and 41-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

This Office action is in response to the communication filed July 16, 2001, Paper No. 11.

Claims 24-50 are pending in the instant application, claims 34-40 have been withdrawn from consideration as being drawn to a non-elected invention, and claims 24-33 and 41-50 have been examined as indicated below.

Response to Amendments and Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claims 24-33 and 41-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the Office action mailed January 30, 2001, Paper No. 9.

Applicant's arguments filed have been fully considered but they are not persuasive. Applicants argue that the term *homolog* has been adequately described in the instant disclosure, in particular at pages 23-25 of the instant specification, and furthermore the claimed invention is enabled over the scope claimed, which scope includes methods of detecting the presence of antibodies to virulent Mycobacterium in a biological comprising detecting antibodies which bind

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to the protein encoded by SEQ ID NO: 2, or detecting the binding of any antibodies that bind to any antigenic determinant or homolog of SEQ ID NO: 2. The term *homolog* is discussed in the instant specification, as Applicants assert. But homologs to SEQ ID NO: 2 have been described in the instant specification to include most bacterial ATPases as well as mammalian ATPases.

Contrary to Applicants' assertions, then, the identified homologs of SEQ ID NO: 2 are not specific to *Mycobacterium*, and therefore the ability to detect antibodies to homologs of SEQ ID NO: 2, which include ion motive ATPases which appear to span large parts of the phylogenetic scale, will not necessarily enable one to detect virulent *Mycobacteria*, but instead will suggest that an antigenic determinant of an ATPase has been detected.

Claims 24-33 and 41-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the presence of antibodies to *Mycobacterium bovis* and *M. tuberculosis*, does not reasonably provide enablement for a method of detecting the presence of antibodies to all *Mycobacteria*, for the reasons set forth in the Office action mailed January 30, 2001, Paper No. 9.

Applicant's arguments filed have been fully considered but they are not persuasive. Applicants argue that the protein of SEQ ID NO: 2 did not react with sera from normal individuals, nor other mycobacterial antibodies. These findings suggest that the antigenic determinants provided by SEQ ID NO: 2 distinguish this polypeptide (ATPase) from other homologs identified by the sequence alignments performed in the instant disclosure. Therefore, the broad claims made in the instant claims, that detection of antibody recognition of any

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homolog of SEQ ID NO: 2 is indicative of the presence of a subset of Mycobacteria, namely virulent Mycobacteria, appears to be incorrect. Therefore, the full scope of the claimed invention, which scope includes the immunogenic detection of any homolog of SEQ ID NO: 2, is not enabled for detecting the presence of virulent Mycobacteria, but of detecting the presence of an ion motive ATPase or homolog thereof.

Allowable Subject Matter

Claim 50 is allowed.

Election/Restriction

This application contains claims 34-40 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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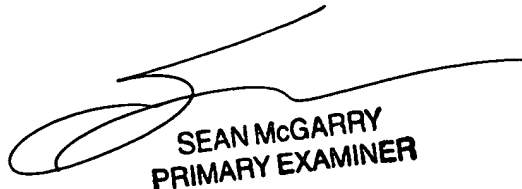
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

October 18, 2001


SEAN MCGARRY
PRIMARY EXAMINER